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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-645,590	08/25/2000	Markku Koulu	2630-106	3991

6449 7590 11-19-2002

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/19/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary

Application No.

09/645,590

Applicant(s)

KOULU ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6,8-13,15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7 and 14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2000 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group II in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the inventions of the different groups are not all unrelated. This is not found persuasive because applicant has not provided any specific arguments why those reasons specifically relied upon in the restriction mailed 8/6/02 are improper. Applicant also argues that the examination of all the restricted inventions would not be a serious burden on the office, but, as shown in the restriction mailed 8/6/02 the different groups are differently classified rendering the searches for those different groups to be not coextensive, for example.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 5, 6, 8-13, 15 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

The citation of subject matter in this application at page 5, lines 15-24, appears to be reference material that is essential for the practice of the instant invention (i.e. NPY receptor antagonists). It is noted that applicant has not made a statement that these references have been incorporated by reference and

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further even if such a statement had been made it would have been improper since the information is essential and the information is included in nonpatent literature (See MPEP 608.01(p). It is noted that any amendment to include the subject matter in these references would be considered new matter in the instant specification.

Claims 1, 2, 4, 7, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is drawn to the use of NPY receptor antagonists in a method of modulating NPY in a subject with an overactive NPY system. The instant specification fails to properly disclose or describe such compounds and further fails to describe how such compound would be used in the methods claimed. The specification simply does not provide this disclosure. The instant specification fails to provide one in the art a description based on chemical structure or otherwise compounds that would be NPY receptor antagonists. It is noted that applicant has made references to prior art but has not properly described those essential compounds in the instant specification.

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Claims 1, 2, 4, 7, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is not enabled since one in the art can not use that which has not been described.

The instant invention is drawn to the use of NPY receptor antagonists in a method of modulating NPY in a subject with an overactive NPY system. The instant specification fails to properly disclose or describe such compounds and further fails to describe how such compound would be used in the methods claimed. The specification simply does not provide this disclosure. The instant specification fails to provide one in the art a description based on chemical structure or otherwise compounds that would be NPY receptor antagonists. It is noted that applicant has made references to prior art but has not properly described those essential compounds in the instant specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 rejected under 35 U.S.C. 102(b) as being anticipated by Soppet et al [WO 96/34877].

Soppet et al disclose a method of treating a patient with inhibitors of NPY receptor in claims 20 and 21, and at pages 24-26, for example.

Claims 1, 2, 7, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soppet et al [WO 96/34877] and Koulu et al [US 6,046,317].

Soppet et al have taught the inhibition of NPY receptor via NPY receptor antagonists at claims 20 and 21, and at pages 24-26. It has been taught at page 25-26, for example, that abnormal conditions such as obesity can be treated with NPY receptor inhibitors since neuropeptide receptor polypeptides of their inventions may bind NPY which was known to be the most potent known substance to cause an increase in feeding behavior, for example.

Koulu et al have taught a method for screening for diagnosing a predisposition for increased serum cholesterol or LDL cholesterol levels in a human via detecting position 7 leucine for proline mutation in NPY.

It would have been obvious to treat conditions such as obesity , hyperlipidemia and LDL levels via NPY receptor antagonists since it has been taught in the art to inhibit NPY receptor to control NPY activity by Soppet et al and since it would further have been obvious to treat conditions specifically related to 7 leucine for proline mutation in NPY since it has been taught by Koulu et al that such mutants are responsible for increased serum cholesterol, for example. One would have had a reasonable expectation of success since

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Soppet et al have disclosed that inhibition of NPY receptor is a reasonable target for treating conditions caused by NPY activity, for example.

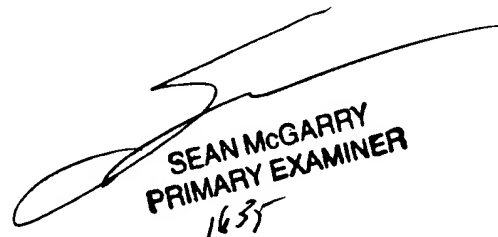
The invention as a whole would therefore have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
November 18, 2002


SEAN MCGARRY
PRIMARY EXAMINER
1635